UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/319,541	08/19/99	MULLER R	62-659-50781

020736
MANELLI DENISON & SELTER
2000 M STREET NW SUITE 700
WASHINGTON DC 20036-3307

HM12/0605

EXAMINER	
SHARAREH, S	
ART UNIT	PAPER NUMBER
1619	14

DATE MAILED: 06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/319,541	Applicant(s) Muller et al
	Examiner SHAHNAM SHARAREH	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 7, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 4-9, 11-13, and 15-25* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 4-9, 11-13, and 15-25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The Amendment filed on March 7, 2001 has been entered. Claims 1, 2, 13, 19-24 are amended. Claims 19-25 are added. Claims 1-2, 4-9, 11-13, 15-25 are pending.

Response to Arguments

1. Any rejection that is not addressed in this Office Action is considered obviated.

2. Claims 1-2, 4-9, 11-12, 17, 19-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by McClelland et al WO 94/00111 . Applicant's arguments have been fully considered, but are not found persuasive.

Applicant argues that while both McClelland's particles and the present formulation may contain similar groups of excipient and they both possess spherical form, it does not necessarily imply that the product themselves are identical and have identical functional properties. In reply, Examiner does not dispute whether particles containing similar groups of excipient and possessing similar physical shape can be distinct, rather, Examiner states that to show a distinctness between prior art and a claimed inveniton; either the language of pending claims must clearly establish distinctness, or adequate evidence must be provided to prove dissimilarities between cited art and claimed invention. Applicant has not met his burden to show such distinctness between the cited art and the instantly claimed invention. Applicant's arguments amount to mere allegation and speculation and that does not show distinctness between the cited prior art and the instant claims.

Applicant specifically argues that McClelland's method of preparation is different than the method of preparation of the instant particles, and McClelland's method results in the

formation of coherent matrix material phase and an incoherent excipient and active substance. In response, Examiner first states that none of the rejected claims are directed to a method of preparation. Second, the instant compositions appear to contain limitations in the form of "product-by-process". Accordingly, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113). If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, McClelland disclose all components of the instant composition. Even though, McClelland does not specifically states that their compositions are formed by "spray drying", they indicate that their microparticles must be dried into spherical form, *(page 3, lines 30-32).* McClelland's compositions comprise all components of the instantly claimed formulation, therefore, his composition inherently possess the same structure and the same functional limitations as presently claimed formulation. No evidence is provided to show a difference in structure or otherwise establish the contrary. Furthermore, the open language of the instant claims does not exclude any type of polymers in the instant formulations, therefore, applicant's argument that McClelland discloses spherical multiparticulates consisting of charged resins is not commensurate with the scope of the claims.

Finally Applicant's assertion that Examiner statement about the particles of McClelland "having unexpectedly good flow" had no support by any facts and should be withdrawn, was noted. In response, Examiner states that Applicant appears to mis-characterized the nature of

Examiner's response. First, Examiner merely restated Applicant's grounds for arguments set forth in Paper No. 8 (p. 7, Th line from the end). Therefore, this issue was first brought up by the Applicant as his ground for traversal. Second, Examiner drew an inference that since McClelland discloses the same exact components, then, his formulation meets the functional characteristics of the instantly claimed formulations, one of which, as previously argued, and instantly claimed, is "unexpectedly good flow properties".

Examiner believes this analysis is based on sound legal reasoning; nevertheless, to prove his conclusion Examiner draws Applicant's attention to Remington: The Science and Practice of Pharmacy, 19th edition, vol. II, Chapter 92, page1627, 2nd column. Applicant is informed that extra reference or evidence can be used to show an inherent characteristic of the thing taught by a reference. "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Continental Can Co. USA v. Monsanto Co.,20 USPQ2d 1746, 1749 (Fed. Cir. 1991) see MPEP § 2124. Remington teaches that "..spheronization is a form of pelletization referring to the formation of spherical particles from wet granulations [method used by McClelland]. Since the particles are round, they have good flow properties when dried....." McClelland's particles are eventually dried and they are spherical, therefore, they possess good flow properties. Accordingly, Examiner maintains his inference that McClelland's particles meets the functional limitation of the instant claims; including the "good flow properties".

Finally, Applicant has not defined what is the metes and bounds for the limitation "controlled-release property", therefore, said term is "given its broadest reasonable interpretation consistent with the art in view of specification". The instant limitation of "providing controlled-release properties when directly compressed"is met by McClelland, because he specifically states that charged resins are added to modulate medicament release from his drug delivery systems (*abstract*). In conclusion, claims 1-2, 4-5, 6-9, 11-12, 17, 19-20 stand rejected.

3. Claims 1-2, 5, 6-9, 11-12, 17-20 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sparks US Patent 5,505,962 . Applicant's arguments have been fully considered, but are not found persuasive.

Applicant argues that the present invention achieves controlled release by a very different mechanism than Sparks. In reply, Examiner states that the instant claims are not limited to achieving controlled release by a mechanism, rather a formulation with controlled release property. Thus, such argument is not commensurate within the scope of the pending claims, because the instant claims are not limited to argued characteristics.

Sparks discloses dry granules comprising an active drug (potassium chloride), with an excipient (magnesium stearate), and a polymer (povidone which is polyvinylpyrrolidone) (*see example 1, col 6, lines 1-20)*. Then Sparks discloses compression of his granule blend into oval tablets which provide controlled release properties (*col 6, lines 21-30, claim* 1). Sparks active drug (potassium chloride) is in direct association with his excipient (*col 8, line55-58*), therefore, they are coherent. Accordingly, Sparks meets all the elements of the instant claims and phases, therefore they inherently meet all functional characteristics of the instant compositions. Besides,

if the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Id. Thus, different process of making the composition does not make the composition patentable over the cited prior art. In conclusion, claims 1-3, 5, 6-9, 11-12, 17-20 stand rejected.

4. Claims 1-2, 5, 6-9, 11-12, 17-20 stand rejected under 35 U.S.C. 102(e) as being anticipated by Motta US Patent 5,662,935. Applicant's arguments have been fully considered, but are not found persuasive.

Applicant argues that Motta uses different process of making. Examiner replies that if the product is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. The controlled release formulation of Motta comprise an active agent, a filler agent such as lactose or a polysaccharide matrix, and a triglyceride moiety to influence the hydrophilic/lipophilic properties of the composition,(*claims 1, 5, 8, 17-18)*. Motta further discloses that his compositions can be crushed to form a granulate or powder with delayed or controlled release properties *(abstract)*. Motta's mixture comprise excipient (spray dried, free flowing lactose) in direct contact with active drug (indomethacin)(*col 8 lines 63-66, example 1*). Therefore his excipient and active drug are coherent. Motta's polymers are then added to provide delayed release properties, thus, they are incoherent (*claim 4*), and finally when the tablet is crushed they still maintain their original characteristics (*abstract, col 4, lines 28-35, lines 53-67*). Thus, Motta meets the limitations set forth in the instant claim. In conclusion, claims 1-2, 4-9, 11-12, 17-20 stand rejected.

5. Claims 1-2, 4-9, 11-13, 15-20, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al US Patent 5,958,458. Applicant's arguments have been fully considered but are not found persuasive.

Applicant argues that just because Norling teaches controlled release does not mean that the structure of Norling's pellets is identical to the claimed invention. Applicant further adds that something can have an identical property but being completely different in structure. Applicant brings examples directed to reservoir patch and laminated patches. These arguments are not found persuasive. First, the instant claims are not directed to patches. Second, Norling not only discloses same components but also same methods of preparing pellets (*abstract, example 1, 12*). Therefore, Norling meets all the limitations of the instant claims. Moreover, Applicant has not met his burden to show distinctness between the cited art and the instantly claimed invention. Mere allegation and speculation does not show distinctness between the cited prior art and the instant claims.

Norling discloses theophylline (an active drug) with calcium carbonate (an excipient) and PVP (a polymer) dissolved in water, and then spray dried to produce particles or pellets friability of which was found to be 2.5% after 5 minutes testing. Norling also discloses that his pellets are free flowing (*col 17, lines 55-60*; *example 3; col 26, lines 10-67, line 60-67, col 21, lines 19-45*). Further, Norling discloses forming a tablet by direct compression of his pellets (*example 12*). Norling discloses inert diluent or fillers in combination with granulating or disintegrating agents or binding agents including cellulose derivatives, and an active substance, *(col 6 lines 20-65, col*

7 lines 1-65, col 9 lines 40-65, col 13 lines 40-65). Norling meets all limitations set forth in the instant claims.

6. Claims 1-2, 4-9, 11-13, 15-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al US Patent 5,958,458. Applicant's arguments have been fully considered but are not found persuasive.

As set forth in Office Action filed on November 22, 2000, although, Norling et al do not specifically teach the optional ingredient, cellulose derivatives in concentrations of 78-90%, however, they do teach the use of cellulose derivatives as a binding agent in the core component of their composition. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the appropriate amount of cellulose material by routine experimentation. Since using cellulose derivatives in oral dosage form is conventional, one of ordinary skill in the art would have had a reasonable expectation to succeed in modifying its concentration to form a sustain release dosage form that provides suitable releasing properties.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claim 12, 17-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12, 17-18 appear to be improperly dependent on claim 1, 2, 19-22. Claim 1 recites that the formulation is in the form of a "freely flowable powder of spray dried particles". However, claim 12, 17-18 requires the formulation to be in the form of a "compressed unit", or "

a tablet or a larger matrix or unit dose". It is not clear in what type of formulation is the claimed compositoin in fact exist? compressed unit (tablet) or free flowable powder? Further, in how many forms can a formulation exist in a single invention? It appears that claims 12, 17-18 are directed to both a powder and a tablet formulation. Claims are thus as a whole indefinite.

Conclusion

8. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The recitation of "free flowing powder" has modified the scope of the claims. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant is requested to provide a copy of all pending claims in response to this Office Action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703)

306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

sjs 5/18/2001